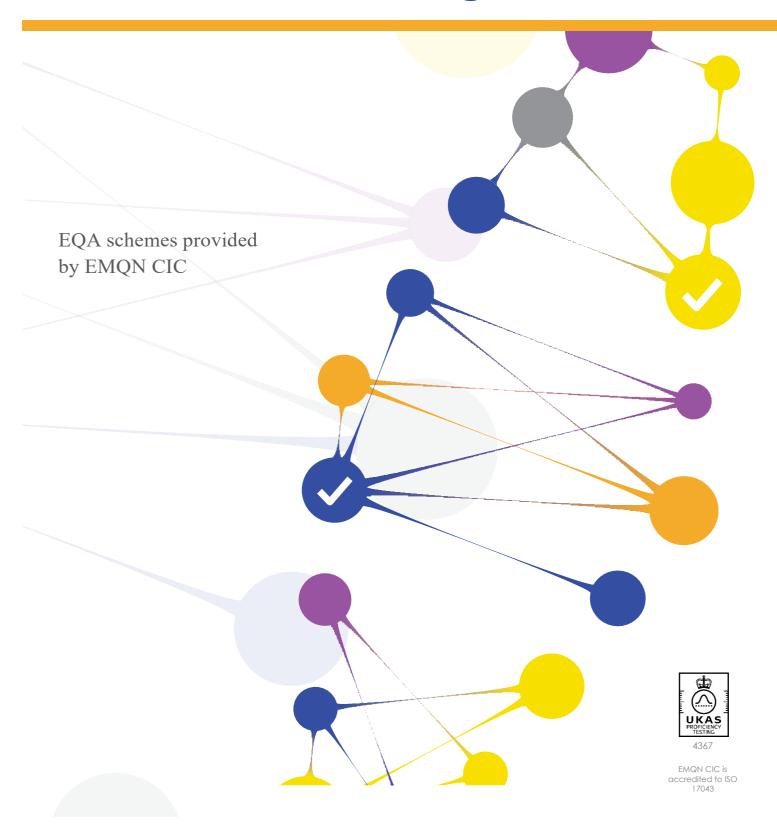


EQA scheme catalogue 2024







Overview

We provide External Quality Assessment (EQA) for 8 core areas of genomic medicine:

- Genomic and inherited disorders (rare diseases)
- Molecular pathology (tissue, plasma)
- Pharmacogenetic testing (drug intolerance)
- Prenatal testing (including non-invasive testing)
- Postnatal testing
- Technology (including Next Generation Sequencing)
- Interlaboratory comparison (sample exchange)
- Variant classification and interpretation

Our EQA schemes:

- Aim to mimic real clinical testing as closely as possible with laboratories testing samples accompanied by an appropriate referral, and for the majority of our schemes subsequently submitting fully interpreted clinical laboratory reports to our website. A subset of technical schemes focus on genotyping and/or benchmarking the analytical process.
- We provide materials that cover the range of common referrals e.g., molecular pathology, diagnostic, predictive, family follow up/cascade screening
- Schemes are educational, sharing information on common genotyping and interpretation errors and ensuring clerical inaccuracy does not lead to patient harm. Additionally, where we have permission, good laboratory reports are shared between participants
- Scheme reports offer data on use of different assays, errors, sensitivity/LOD of the assays
- In technical schemes benchmarking of data is provided against other labs or over time
- Assess interpretation and follow up/advice by measuring compliance against best practice and giving directed educational feedback what is wrong and why it is wrong.
- Where possible we offer multi-language support to allow laboratories to submit their reports in their native language.
- Most of our schemes are covered under our UKAS accreditation (ISO 17043:2010)

DOC2674 EQA Scheme catalogue 2024





New for 2024

We continue to expand the scope of our EQA schemes to meet the needs of our users and address the increasing use of NGS panel testing and clinically-focused genomic methods. For 2024 the changes to our portfolio are as follows (detailed information available from https://www.emqn.org/participating-in-eqa/):

Scheme	New	Extension to scope	Description of change for 2024
Hereditary Amyloidosis	✓		Pilot EQA scheme.
Rare neuromuscular disorders	√		Pilot EQA scheme. Collaboration with European Reference Network-Neuromuscular Diseases (ERN EURO-NMD).
Hereditary hearing loss		✓	Hereditary deafness (2023) scheme renamed "Hereditary hearing loss" to better reflect the group of disorders, and the adoption of panel testing.
Pharmacogenetics (<i>DPYD</i> / <i>UGT1A</i> testing only)	✓		Pilot EQA scheme. <i>DPYD/UGT1A1</i> testing in context of pharmacogenetics.
DNA Sequencing - NGS (v Germline) Copy Number Variants (CNV)	✓		Pilot EQA scheme. Germline CNV (>50bp in size) testing. Collaboration with GenQA.
Breast cancer (AKT Pathway testing)		✓	PIK3CA scheme renamed and extended to include AKT1 and PTEN testing in tissue.
Breast cancer (ESR1 testing)	√		Pilot EQA scheme. ESR1 testing in plasma.
Urothelial / bladder cancer (FGFR testing)	✓		Pilot EQA scheme. <i>FGFR</i> testing in tissue. Supported by Janssen

Pricing/Fees

EMQN is a community interest company (CIC) registered in England (Number: 12020789, VAT / Tax Number: 329563282). As a CIC, we recognise the financial constraints being imposed upon many laboratories and therefore we keep our participation fees as low as possible. Consequently, we offer a number of options to help laboratories manage the costs of EQA participation and EMQN membership.





Examples include:

- Membership of EMQN is FREE. You must be a member of EMQN to purchase our EQAs.
- We offer a 7.5% discount for 6 or more EQA schemes purchased, with this increasing to a 15% discount when 12 or more EQA schemes have been purchased. To qualify for theses discounts you must purchase all schemes in one order. Note: ILC activities (see page 12 do not qualify for a discount).
- **Discounted participation** in our EQA activities for laboratories in developing / evolving economies (see https://www.emqn.org/participating- in-eqa/discounted-costs-participation/ for more information).
- Some EQA schemes are free, or participation costs are subsidised by sponsorship from corporate sponsors.

EMQN partners with several distributor organisations worldwide to make shipping, billing and invoicing easier in certain regions. Where distributor arrangements exist, then there may be differences in the pricing structure due to VAT/Tax, logistics and handling costs. For more information, please contact us (office@ emqn.org) or see our website (https://www.emqn.org/participating-in-eqa/terms-conditions/).

Guidance for genotyping-only laboratories

Genetic test reports may be transmitted to other non-genetics health professionals and may also cross national boundaries. Therefore, whilst we recognise the different legislative requirements in various parts of the world, it is EMQN policy to encourage a comprehensive 'stand-alone report' following relevant best practice guidance, where available. Most of our EQA schemes therefore require interpretation of the genotype in the context of the clinical information provided.

However, genotyping-only laboratories can still take part in our EQA schemes by submitting a supporting document to the relevant scheme explaining why they do not provide clinical interpretation. Please note laboratories submitting genotyping reports are required to classify the variants they have detected and include those that are of clinical significance in their reports.

Guidance for commercial kit manufacturers

Participation in EQA schemes is a valuable activity for commercial kit manufacturers and can be used for both validation of new test methodologies, as well as post market surveillance of existing products to ensure compliance with the requirements of the *In-vitro* Diagnostics Regulation (IVD-R).

We welcome and encourage the participation of commercial kit manufacturers with EMQN - we usually require a declaration of reason for use of the EQA and there is normally no requirement to provide clinical interpretation of test results. If you would like to discuss this further, then please contact us.





- 1. Go to the EMQN website: https://www.emqn.org
- 2. Click the "LOGIN" button, enter your username and password, and go to the "Purchase" page. **Please note** that both the main contact person <u>AND</u> additional staff members registered to the account can register for schemes. **Note:** only staff with permissions to purchase schemes will see the Purchase page.
- 3. If you do not remember your password, click 'Forgotten your password' on the login page.
- 4. Select the schemes you wish to participate in. **IMPORTANT:** click the "Check out and Complete" button to finalize the registration.
- 5. The **registration period is open from 18**th **September 2023.** The closing date is dependent on the scheme please see the website for details.
- 6. All participating laboratories are required to pay the appropriate fees to register. When a registration form is submitted, we assume that your laboratory will participate in the scheme, and materials are prepared accordingly. Therefore, a registration fee has to be paid, regardless of whether you submit results or not. If your laboratory circumstances change, you can request to be removed from a scheme by contacting office@emqn.org before samples are dispatched. However, if samples have been dispatched the fees will be charged.
- 7. An invoice will be prepared (including those schemes that have not been dispatched yet) and sent by email in April 2024. Laboratories with distribution agents will receive an invoice directly from them.
- 8. EQA materials will be sent to the laboratories in January, May, June, September or October 2024 (depending on EQA scheme) and should be analysed by your laboratory's routine protocol.
- 9. The laboratory is required to document results (usually clinical case reports) as per routine diagnostic reports and submit them to the EMQN website before the reporting deadline.
- 10. Validated genotypes of EQA materials will be published shortly after the reporting deadline and detailed results will be available 3-4 months afterwards.
- 11. For full details of all the schemes, please see the online EQA scheme catalogue that is available from https://www.emqn.org.







Genomic and Inherited disorders EQA schemes

These EQA schemes require genomic DNA samples to be genotyped and full interpretative reports to be submitted. Genotyping, Interpretation and Clerical Accuracy are assessed by EMQN. We collaborate with other organizations to provide some of these EQA schemes. Please see www.emqn.org/participating-in-eqa/ for more information.

Scheme	Registration Period	Distribution month	Results deadline	ISO 17043 status	Fee (GBP)
Autosomal dominant polycystic kidney disease	18.09.2023 - 30.11.2023	January	March	☆ Accredited	440
Beckwith-Wiedemann and Silver-Russell syndromes	18.09.2023 – 30.11.2023	January	March	♠ Accredited	440
Cardiac genetics (arrhythmias)	18.09.2023 – 30.11.2023	January	March	☆ Accredited	440
Cardiac genetics (hypertrophic cardiomyopathies)	18.09.2023 – 30.11.2023	January	March		440
Charcot-Marie-Tooth disease / Hereditary Neuropathy with liability for pressure palsies	18.09.2023 – 30.11.2023	January	March	♠ Accredited	440
Congenital Adrenal Hyperplasia	18.09.2023 – 30.11.2023	January	March	♠ Accredited	440
Duchenne / Becker Muscular Dystrophy	18.09.2023 – 30.11.2023	January	March	☆ Accredited	440
Ophthalmological disease: Inherited Retinal Disorders (IRD)	18.09.2023 – 28.02.2024	September	November	⊗ Not accredited	01
Familial autosomal dominant hypercholesterolemia	18.09.2023 – 30.11.2023	January	March		440
Familial SHOX gene related disorders	18.09.2023 – 30.11.2023	January	March	☆ Accredited	440
Fragile X Syndrome	18.09.2023 – 30.11.2023	January	March		440
Friedreich Ataxia	18.09.2023 – 30.11.2023	January	March		440

¹ Limited to 100 places. Funded by an unrestricted grant from corporate sponsor.



TEL: +44 161 757 1591

WEB: www.emqn.org
EMAIL: office@emqn.org





Scheme	Registration Period	Distribution month	Results deadline	ISO 17043 status	Fee (GBP
Hereditary amyloidosis NEW	18.09.2023 - 30.11.2023	January	March	⊗ Not accredited	275
Hereditary breast / ovarian cancer (panel testing)	18.09.2023 – 30.11.2023	January	March	♠ Accredited	440
Hereditary breast / ovarian cancer (targeted BRCA testing ONLY)	18.09.2023 – 30.11.2023	January	March	② Accredited	440
Hereditary deafness	18.09.2023 – 30.11.2023	January	March	☆ Accredited	440
Hereditary Haemochromatosis	18.09.2023 – 30.11.2023	January	March	[™] Accredited	440
Huntington disease	18.09.2023 - 30.11.2023	January	March	[™] Accredited	440
Lynch syndrome (hereditary non-polyposis colon cancer)	18.09.2023 - 30.11.2023	January	March	[™] Accredited	440
Mitochondrial DNA metabolic disorders	18.09.2023 – 30.11.2023	January	March	⊗ Accredited	440
Monogenic Diabetes	18.09.2023 - 30.11.2023	January	March	[™] Accredited	440
Multiple Endocrine Neoplasia Type 2	18.09.2023 – 30.11.2023	January	March	[™] Accredited	440
Myotonic dystrophy (Types 1 and/or 2)	18.09.2023 – 30.11.2023	January	March	⊗ Accredited	440
Osteogenesis imperfecta	18.09.2023 – 30.11.2023	January	March	☆ Accredited	440
Phenylketonuria	18.09.2023 - 30.11.2023	January	March	☆ Accredited	440
Polyposis Syndromes	18.09.2023 - 30.11.2023	January	March	⊗ Accredited	440
Porphyrias	18.09.2023 - 30.11.2023	January	March	☆ Accredited	440
Prader-Willi and Angelman Syndromes	18.09.2023 - 30.11.2023	January	March	(Accredited	440
Rare neurological disease genes	18.09.2023 – 30.11.2023	January	March	⊗ Not accredited	440
Rare neuromuscular disease genes NEW	18.09.2023 – 30.11.2023	January	March	⊗ Not accredited	275





Scheme	Registration Period	Distribution month	Results deadline	ISO 17043 status	Fee (GBP)
Retinoblastoma	18.09.2023 – 30.11.2023	January	March	☆ Accredited	440
RYR1 related Myopathies and Malignant Hyperthermia susceptibility	18.09.2023 – 30.11.2023	January	March	② Accredited	440
Severe Combined Immunodeficiencies	18.09.2023 – 30.11.2023	January	March	(2) Accredited	440
Spinal Muscular Atrophy	18.09.2023 – 30.11.2023	January	March	☆ Accredited	440
Spinocerebellar Ataxia's	18.09.2023 - 30.11.2023	January	March	② Accredited	440
Stickler syndrome	18.09.2023 - 30.11.2023	January	March	(2) Accredited	440
Systemic Autoinflammatory Diseases	18.09.2023 - 30.11.2023	January	March	(2) Accredited	440
Von Hippel Lindau Syndrome	18.09.2023 – 30.11.2023	January	March	(2) Accredited	440
Wilson Disease	18.09.2023 – 30.11.2023	January	March		440
Y-Chromosome Microdeletion testing	18.09.2023 – 30.11.2023	January	March	(Accredited	440





These EQAs require FFPE, Plasma, or germline DNA samples to be genotyped and fully interpretative reports are to be submitted (exceptions may apply – see website for comprehensive details on each scheme). We collaborate with other organizations to provide some of these EQA schemes. This is clearly shown for each EQA scheme. Please see www.emqn.org/participating-in-eqa/ for more information.

TISSUE (FFPE)

Scheme	Registration Period	Distribution month	Results deadline	ISO 17043 status	Fee (GBP)
Breast cancer (AKT Pathway gene testing - PIK3CA, AKT1, PTEN)	18.09.2023 – 28.02.2024	June	August	Accreditation pending	275 ²
Colorectal cancer	18.09.2023 – 28.02.2024	June	September	[™] Accredited	610
Lung cancer - CORE	18.09.2023 – 28.02.2024	June	September	⊗ Accredited	275 ³
Lung cancer- NEW / EMERGING BIOMARKERS	18.09.2023 - 28.02.2024	June	September	(a) Accredited	125 ⁴
Melanoma	18.09.2023 – 28.02.2024	June	September	⊗ Accredited	610
Microsatellite Instability testing	18.09.2023 – 28.02.2024	June	September	⊗ Accreditation pending	440
Oncogene Panel Testing	18.09.2023 – 28.02.2024	June	September	⊗ Accredited	610
Ovarian, breast, prostate and pancreatic cancers (Somatic testing of <i>BRCA1</i> , <i>BRCA2</i>) (PARPi)	18.09.2023 – 28.02.2024	September	November	② Accredited	05
Urothelial / bladder cancer (FGFR testing) ^{NEW}	18.09.2023 – 28.02.2024	September	November	⊗ Not accredited	06

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² Limited to 200 places. Partial subsidized by sponsorship from Novartis

³ Limited to 450 places. Partial subsidized by sponsorship from Amgen.

⁴ Limited to 450 places. Partial subsidized by sponsorship from Amgen. You must purchase Lung cancer – CORE scheme to qualify for this scheme.

⁵ Limited to 400 places. Funded by sponsorship from MSD, and Astrazeneca.

⁶ Limited to 30 places. Funded by sponsorship from Janssen.





PLASMA (cfDNA)

Scheme	Registration Period	Distribution month	Results deadline	ISO 17043 status	Fee (GBP)
Breast cancer (ESR1)	18.09.2023 – 28.02.2024	September	November	⊗ Not accredited	275
Lung cancer (EGFR, KRAS)	18.09.2023 – 28.02.2024	September	November	⊗ Not accredited	275
Prostate cancer (BRCA1, BRCA2) (PARPi)	18.09.2023 – 28.02.2024	September	November	Not accredited	07

Germline DNA

Scheme	Registration Period	Distribution month	Results deadline	ISO 17043 status	Fee (GBP)
Ovarian, breast, prostate and pancreatic cancers (germline testing of BRCA1, BRCA2, and other HRR genes) (PARPi)	18.09.2023 – 28.02.2024	September	November	ⓒ Accredited	2008

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 $^{^7}$ Limited to 75 places. Funded by sponsorship from MSD, and Astrazeneca 8 Limited to 320 places. Partial subsidized by sponsorship from MSD, and Astrazeneca





Pharmacogenetics EQA Schemes

Our EQA schemes require DNA samples to be genotyped and full interpretative reports to be submitted. We collaborate with other organizations to provide some of this EQA scheme. This is clearly shown - please see www.emqn.org/participating-in-eqa/ for more information.

Scheme	Registration Period	Distribution month	Results deadline	ISO 17043 status	Fee (GBP)
Pharmacogenetics (panel testing)	18.09.2023 – 28.02.2024	June	September	Accreditation pending	440
Pharmacogenetics (<i>DPYD</i> / <i>UGT1A1</i> testing only) ^{NEW}	18.09.2023 – 28.02.2024	June	September	⊗ Not accredited	440





These EQAs require DNA, FFPE, or fresh frozen samples to be tested and genotyped only. We collaborate with other organizations to provide some of these EQA schemes. This is clearly shown for each EQA scheme. Please see www.emqn.org/participating-in-eqa/ for more information.

Scheme	Registration Period	Distribution month	Results deadline	ISO 17043 status	Fee (GBP)
DNA Sequencing (Sanger)	18.09.2023 – 28.02.2024	June	September	☆ Accredited	440
DNA Sequencing (NGS v Germline SNVs and Indels)	18.09.2023 - 28.02.2024	September	November	Accreditation pending	650
DNA Sequencing (NGS v Germline) – CNV testing NEW	18.09.2023 – 28.02.2024	September	November	⊗ Not accredited	650
DNA Sequencing (NGS v Somatic SNVs and Indels– no match germline sample)	18.09.2023 – 28.02.2024	September	November	⊗ Not accredited	650
DNA Sequencing (NGS v Somatic SNVs and Indels + matched germline sample)	18.09.2023 – 28.02.2024	September	November	⊗ Not accredited	1050





These EQAs require plasma samples to be genotyped and full interpretative reports to be submitted. We collaborate with other organizations to provide some of these EQA schemes. This is clearly shown for each EQA scheme. Please see www.emqn.org/participating-in-eqa/ for more information.

Scheme	Registration Period	Distribution month	Results deadline	ISO 17043 status	Fee (GBP)
NIPT for common aneuploidies (including sex chromosomes)	18.09.2023 – 28.02.2024	October	November	Accreditation pending	455
NIPT for fetal sexing (X- linked disorders)	18.09.2023 – 28.02.2024	October	November	Accreditation pending	455
NIPT for fetal rhesus D (RhD) status ^{NEW}	18.09.2023 – 28.02.2024	October	November	Not accredited	455

Postnatal testing EQA Schemes

This EQA requires DNA samples to be genotyped and full interpretative reports to be submitted. We collaborate with another organization to provide this EQA scheme. This is clearly shown - please see www.emqn.org/participating-in-eqa/ for more information.

Scheme	Registration Period	Distribution month	Results deadline	ISO 17043 status	Fee (GBP)
Postnatal Constitutional CNV detection [array / NGS]	18.09.2023 – 28.02.2024	May	July	⊗ Accredited	455





EMQN provides these EQA activities where there are a small number of laboratories performing testing, and/or there are no EQA schemes available. The sample types vary (normally DNA) and EMQN facilitates the exchange of materials between laboratories for the ILC, plus assessment of the genotyping results, and provision of a report summarizing the results. If you are interested in additional ILC activities, please complete our "Expression of interest form". Please see www.emqn.org/participating-in-eqa/ for more information.

ILC	Registration Period	Distribution month	Results deadline	ISO 17043 status	Fee (GBP)
Achondroplasia (FGFR3)	Variable - contact us	Variable - contact us	Variable - contact us	⊗ Not accredited	305
Congenital central hypoventilation syndrome (CCHS) (PHOX2B)	Variable - contact us	Variable - contact us	Variable - contact us	⊗ Not accredited	305
Fascioscapulohumeral Muscular Dystrophy (Type 1)	Variable - contact us	Variable - contact us	Variable - contact us	⊗ Not accredited	305
Fascioscapulohumeral Muscular Dystrophy (Type 2)	Variable - contact	Variable - contact us	Variable - contact us	⊗ Not accredited	305





Variant Classification and Interpretation

EMQN provides an educational individual competence assessment programme designed to assess the accuracy of variant classification and interpretation in various clinical scenarios. We collaborate with another organization to provide this activity. Please see www.emqn.org/participating-in-eqa/ for more information.

Scheme	Registration Period	Distribution month	Results deadline	ISO 17043 status	Fee (GBP)
BRCA and HRR gene variant classification	ТВС9	May/October	June/Nove mber	⊗ Not accredited	010

To be confirmed

¹⁰ Funded by an unrestricted grant from MSD and Astrazeneca-





Extra samples

The amount of EQA scheme material we ship for each EQA scheme is based upon the average requirements for routine laboratory testing. In some instances, the amount we ship may not be sufficient (for example, when a laboratory is using a technology which requires higher/larger amounts of input DNA, or which only tests for one gene at a time). In these circumstances, laboratories have the option to purchase EXTRA materials from our catalogue whilst the schemes are open for registration. Extra materials are chargeable and will be invoiced - they are not covered under any of our corporate sponsorship agreements. These materials are priced as follows:

Molecular pathology EQA schemes -	Fee (GBP, £) (extra sets 1, 2, or 3)
Lung Cancer (core/ new emerging)	278, 340, 376
Colorectal Cancer	278, 340, 376
Melanoma	278, 340, 376
Oncogene panel testing	278, 340, 376
Technical EQA schemes	Fee (GBP, £) (extra set
DNA Sequencing (NGS v Germline SNVs and Indels)	134
DNA Sequencing (NGS v Germline CNVs)	134
Molecular genetics EQA schemes	Fee (GBP, £) (extra se
Fragile X Syndrome	134
Friedreich Ataxia	134
Myotonic Dystrophy	134
Other EQA schemes in the catalogue	Fee (GBP, £
EXTRA samples are not available for purchase (except those listed	above) N/A







Replacement samples

From time to time, laboratories may require replacement samples (for example, due to technical error, sample mix ups etc.). Replacement samples cannot be guaranteed but will be sent if available. Refer to the scheme instructions for information on how to request a replacement sample. Testing of replacements samples must be within the same timeframe as the originals. There is a charge to cover reasonable costs associated with sending replacement samples and these charges apply per request. This charge is a FLAT RATE independent of geographical location (see below) and will be applied to the requesting laboratory's EMQN invoice. **PLEASE NOTE:** If your organisation has previously raised a **PO number then you may need to adjust this to take account of costs associated with replacement samples.**

Schemes		Fee (GBP, £)
Colorectal and Melanoma	(1-4 samples)	106
	(5-7 samples)	186
	(8-10 samples / full set)	265
Oncogene panel	(1-3 samples / full set)	265
DNA Sequencing (NGS v Somat	ic with matched germline sample)	265
All other non-sponsored EQA s	chemes	75
Fully-sponsored EQA schemes schemes)	(limited to 1 set only, does not apply to partially subsidised	0

Invoices

VAT / Tax

The pricing of all products sold by EMQN (EQA schemes and memberships) is exclusive of VAT/Tax which will be charged on our invoices as follows:

- Customers from the United Kingdom (UK): Our products are liable to VAT and this will be added to all invoices.
- Customers from the European Union (EU): Our products are liable to UK VAT/Tax (20%) unless the customer can supply their VAT/Tax number; those customers will be required to account for VAT/Tax in their own region under the reverse charge scheme. The VAT/Tax number can be updated in the users EMQN website account.
- Customers outside of the EU or UK: VAT/Tax will not be charged on invoices.

Payment terms

Our payment terms are 30 days. There are penalties for late payment and interest (Bank of England base rate plus 1%), charged per month, will be applied to outstanding balances after the invoice payment date. Non-payment of invoices will mean access to your laboratory account will be suspended until payment is received (see section 4.3 of our terms and conditions: https://www.emqn.org/participating-in-eqa/terms-conditions/)





Purchase orders

If you require a purchase order quote to register for the EQA scheme, then please contact us (office@emqn.org).

Other information

EMQN is a community interest company (CIC) registered in England (Number: 12020789. VAT/Tax Number: 329563282).

For more information please contact us (**finance@emqn.org**) or see our website (https://www.emqn.org/participating-in-eqa/terms-conditions/).

Terms and Conditions

EMQN CIC is supported financially by subscription fees. By joining us, and/or registering for an EQA scheme, you are agreeing to abide by our terms and conditions. A copy of our full terms and conditions can be downloaded from our website - please go to the following page (https://www.emqn.org/
participating-in-eqa/terms-conditions/).

Privacy and Data Protection

EMQN is committed to ensuring that your personal information is protected and never misused. We've read lots of Privacy policies and understand that they can be complicated. We've tried to make ours as clear as possible and summarised how EMQN handles your personal information. To read our Privacy Policy, please go to our website - (see https://www.emqn.org/privacy-policy).

Accreditation of EMQN

EMQN is accredited by the United Kingdom Accreditation Service (UKAS) to ISO17043:2010. The scope of our accreditation can be found at https://www.emqn.org/participating-in-eqa/ukas-accreditation/. The accreditation status of all our EQA schemes is clearly shown within each of the schemes listed in this catalogue.



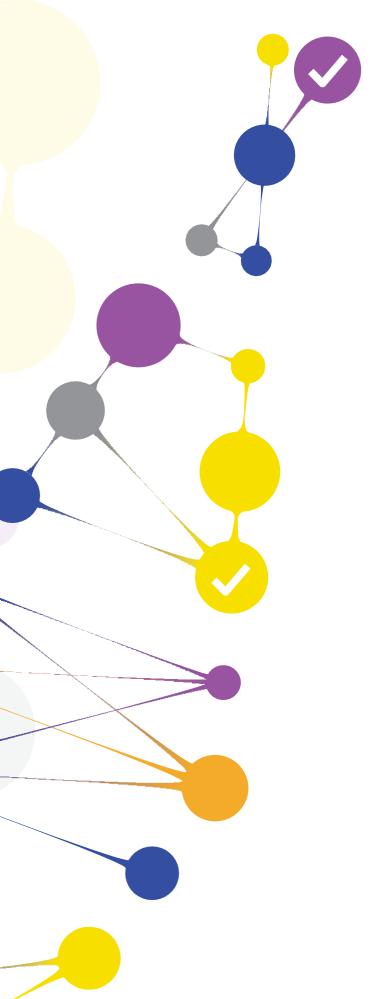
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Working with EMQN

If you would like to join one of our assessment teams, please go to our "Become an EQA Assessor" section of the website for more information.

Help and Advice

Our website has a comprehensive Help and Frequently Asked Questions (FAQ) section, including user guides and short help videos. If you cannot find an answer to your questions, then please do not hesitate to contact us (office@emqn.org). Our staff are always happy to help you.





Registered address:

Unit 4 Enterprise House, Pencroft Way, Manchester Science Park, Manchester, M15 6SE, United Kingdom.

TEL: +44 161 757 1591 WEB: www.emqn.org EMAIL: office@emqn.org

@EMQNOffice . https://www.linkedin.com/company/emqn

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WEB: www.emqn.org EMAIL: office@eman.org